

# PATENT COOPERATION TREATY

REC'D 16 MAR 2006

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PCT

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:  
Laura M. Ginkel  
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RAHWAY, NJ 07065-0907

## PCT

### WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference

PCT 21554

Date of mailing  
(day/month/year)

14 MAR 2006

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US05/00955

International filing date (day/month/year)

12 January 2005 (12.01.2005)

Priority date (day/month/year)

16 January 2004 (16.01.2004)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A16K 39/012, 32/02, 39/395; C12N15/00; C07K 16/20, 14/45, 14/00, 7/00 and US Cl.: 435/7.2, 975; 424/184.1, 269.1, 530/388.6, 822, 403,

Applicant

MERCK & CO., INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I      Basis of the opinion
- ☐ Box No. II      Priority
- ☐ Box No. III      Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV      Lack of unity of invention
- ☒ Box No. V      Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement
- ☐ Box No. VI      Certain documents cited
- ☐ Box No. VII      Certain defects in the international application
- ☐ Box No. VIII      Certain observations on the international application

#### 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

Mail Stop PCT, Attn: ISA/US  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Date of completion of this opinion

Authorized officer

Achuthamurthy ponhathapara

Telephone No. 571-272-1600

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US05/00955-

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed  
☐ a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☒ a sequence listing  
☐ table(s) related to the sequence listing

b. format of material

- ☒ on paper  
☒ in electronic form

c. time of filing/furnishing

- ☒ contained in the international application as filed.  
☒ filed together with the international application in electronic form.  
☐ furnished subsequently to this Authority for the purposes of search.

3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No

PCT/US05/00955

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
- ☐ paid additional fees
  - ☐ paid additional fees under protest and, where applicable, the protest fee
  - ☐ paid additional fees under protest but the applicable protest fee was not paid
  - ☒ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
  - ☒ not complied with for the following reasons:  
See the lack of unity section of the International Search Report (Form PCT/ISA/210)

4. Consequently, this opinion has been established in respect of the following parts of the international application:

- ☐ all parts.
- ☒ the parts relating to claims Nos. 1-6 and 12-23

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/US05/009551

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>12-23</u>	YES
	Claims <u>1-6</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-6, 12-23</u>	NO
Industrial applicability (IA)	Claims <u>1-6, 12-23</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Liberator et al disclose the 5' end of a cDNA from *Eimeria tenella* deposited under the accession No. CD345641.1 showing 100% identity over 556 nucleotides to the casine kinase 1 disclosed by applicants. In addition, Szu-Ting Ng et al disclose a cDNA clone containing an EST deposited in GenBank under the accession No. BG929759.1 from *Eimeria tenella* that shows 100% sequence identity over 510 base pairs to the sequence disclosed by applicants. Therefore a person of skill in the art would have been able to isolate the full length sequence and clone and express the casine kinase 1 from *Eimeria tenella*.